

REMARKS

Reconsideration and the timely allowance of the pending claims, in view of the following remarks, are respectfully requested.

In the Final Office Action dated April 29, 2004, the Examiner rejected claims 13-16, 64-66, 69, and 72-75, 78-79, and 92, under 35 U.S.C. §102(b), as anticipated by Roberts '786 (U.S. Patent No. 4,754,786); rejected claims 13-18 and 63-94, under 35 U.S.C. §103(a), as being unpatentable over Thompson '166 (U.S. Patent No. 4,710,166) in view of Wortrich '643 (U.S. Patent No. 4,750,643); rejected claims 13-18 and 63-94, under 35 U.S.C. §103(a), as being unpatentable over Orkin '444 (U.S. Patent No. 4,925,444) in view of Wortrich '643; and rejected claims 13-18, 64-70, and 72-94, under 35 U.S.C. §103(a), as being unpatentable over Kampfe '847 (U.S. Patent No. 5,450,847) in view of Wortrich '643.

By this Amendment, Applicant has amended claims 13-14, 16, 66-67, 69, 72-73, 75, 79, 80, 82-83, 85, and 89-90 to provide a clearer presentation of the claimed invention. Applicant submits that no new matter has been introduced.

Applicant respectfully traverse the prior art rejections, under 35 U.S.C. §§102(b), 103(a), for the following reasons:

I. Prior Art Rejections Under §102(b).

The Examiner summarily asserted that the Roberts '786 reference anticipates independent claim 13. Applicant respectfully disagrees.

Independent claim 13, as amended, sets forth an injection apparatus for delivering fluid to multiple patients, comprising, *inter alia*:

- (a) ***a reusable portion*, including**
 - a first fluid source;***
 - a second fluid source; and***
 - a device adapted to mix fluids from the first and second fluid source;* and**

(b) at least one per-patient disposable portion having a first end connectable to a patient of the multiple patients and a second end,

wherein, during delivery of the fluids to the patient, the second end of the at least one per-patient disposable portion couples to the reusable portion to define a continual fluid path between the first and second fluid sources and the patient.

As indicated above, amended claim 13 now positively recites that the reusable portion includes the first and second fluid sources and the device adapted while the at least one per-patient disposable portion connects at one end to the patient. Claim 13 also positively recites that, during delivery of the fluid, the second end of the at least one per-patient disposable portion couples to the reusable portion to define a continual fluid path between the first and second fluid sources and the patient.

Unlike the present invention, however, there is nothing in the Roberts '786 reference that teaches or suggests the combination of features recited in claim 13. In particular, the Roberts '786 reference is directed to the *filling of sterilized containers or storage bags*. (See, Roberts '786: col. 1, lines 7-9; col. 5, lines 52-55). Roberts '786 discloses the use of a mixing vessel 44, a reservoir container 50, and a pump 54 that pumps the fluid 12 out of the reservoir container 50 and through a filter element 56 via a tube 54d. The fluid 12 then flows through a conduit element 60, and through a plurality of connector elements 62 into storage bags 10 to fill the bags 10. (See, Roberts '786: col. 5, line 52 – col. 6, line 52; FIG. 4).

Given the intended purpose of the Roberts '786 invention, there is nothing in the reference that teaches the direct dispensation of fluids from the first and second fluid sources directly to the patient. As such, the Roberts '786 reference clearly fails to teach that, during delivery of the fluids to the patient, the second end of the at least one per-patient disposable portion couples to the reusable portion to define a continual fluid path between the first and second fluid sources and the patient, as required claim 13.

For at least these reasons, Applicant submits that the Roberts '786 reference does not teach the claimed combination of elements recited by amended claim 13. Accordingly, Roberts '786 cannot be deemed to anticipate claim 13. Nor can the

Roberts ‘786 reference be combined with any reference of record to render claim 13 unpatentable. Applicant, therefore, respectfully requests the withdrawal of the rejection of claim 13, under §102(b). Moreover, because claims 14-18 and 63-71 depend from claim 13, claims 14-18 and 63-71 are patentable by virtue of dependency as well as for their additional recitations. In addition, independent claims 72 and 82 recite similar features to claim 13, claims 72 and 82 are patentable for at least the reasons given with respect to claim 13. Further, because claims 73-81 depend from claim 72 and claims 83-94 depend from claim 82, claims 73-81 and claims 83-94 patentable by virtue of dependency as well as for their additional recitations.

II. Prior Art Rejections Under §103(a).

The Examiner summarily asserted that the each of the combinations of Thompson ‘166 and Wortrich ‘643, Orkin ‘444 and Wortrich ‘643, and Kampfe ‘847 and Wortrich ‘643 renders independent claim 13 unpatentable. Applicant respectfully disagrees.

Regarding the asserted combination of Thompson ‘166 and Wortrich ‘643, Applicant notes that the Thompson ‘166 reference teaches a system for the *sequential delivery* of two fluids. (See, Thompson ‘166: col. 3, lines 51 – 52). Accordingly, Thompson ‘166 discloses the use of a primary fluid container 20, a primary fluid line 50 extending towards an electronic infusion device 26, a secondary fluid container 22, a secondary fluid line 52 extending from the secondary fluid container 22 towards the device 26, and a Y-connector unit 54. (See, Thompson ‘166: col. 3, line 51 – col. 4, line 20; FIG. 1). In contrast to the Examiner’s assertions, the Y-connector unit 54 is employed to switch between dispensing fluid from the primary fluid container 20 to the secondary fluid container 22 – and has nothing to do with the mixing of fluids.

As such, the Thompson ‘166 reference fails to teach or suggest a reusable portion having a device adapted to mix fluids from the first and second fluid sources, as required by claim 13.

With this said, the Wortrich '643 reference fails to cure the deficiencies noted above regarding the Thompson '166 reference. The Wortrich '643 reference is directed to dispensing fluid **12** from a single container **10** to a succession of multiple patients. (*See, Wortrich '643:* col. 3, line 14 – col. 4, line 39; *see also,* Abstract; FIG. 1). Understandably, Wortrich '643 fails to mention the use of a second fluid source, as required by claim 13. Moreover, much like Thompson '166, the Wortrich '643 reference fails to teach or suggest the use of a reusable portion having a device adapted to mix fluids from the first and second fluid sources, as also required by claim 13.

Regarding the asserted combination of Orkin '444 and Wortrich '643, Applicant notes that the Orkin '444 reference is directed to a closed, multiple-fluid delivery system that can deliver a plurality of preselected fluids in a preselected sequence via a closed fluid-flow delivery system to an output port for a single patient. (*See, Orkin '444:* col. 3, lines 34-38; *see also,* Abstract). The Orkin '444 reference discloses the use of a fluid flow junction member **70** to accommodate the connection of numerous solution containers **56**. (*See, Orkin '444:* col. 10, lines 22-26; FIG. 3). The Orkin '444 reference specifically states that the fluid flow junction member **70** **does not function as a mixing chamber.** (*See, Orkin '444:* col. 12, lines 23-25; FIG. 3). Rather, the mixing of fluids is achieved by dispensing the fluids from containers **56** in a multiplex fashion, through junction member **70** and a pump **84**, and onto tubing member **90**. As the fluids move through the tubing member **90**, the fluids are mixed. (*See, Orkin '444:* col. 22, lines 21-27; col. 23, lines 43-44; FIGs. 11A, 12). It will be appreciated that, based on its location, tubing member **90** is to be considered part of the per-patient disposable portion – not the reusable portion.

As such, the Orkin '444 reference fails to teach or suggest the use of a reusable portion having a device adapted to mix fluids from the first and second fluid sources, as required by claim 13.

Moreover, because the Orkin '444 system is configured to dispense multiple fluids to only a single patient, the combination of Orkin '444 with Wortrich '643 is clearly antithetical to both references. Furthermore, as discussed above, the Wortrich

‘643 reference, on its own, also fails to discuss the use of a device adapted to mix fluids from the first and second fluid sources, as required by claim 13.

Finally, with respect to the asserted combination of Kampfe ‘847 and Wortrich ‘643, Applicant points out that the Kampfe ‘847 reference is directed to a system capable of preparing and mixing suitable dosage forms of fluid contrast medium at a concentration and in an amount which are optimal for the individual examination. (*See, Kampfe ‘847: col. 3, lines 10-20*). There is nothing in Kampfe ‘847, however, that contemplates or suggests *the direct dispensation of fluids to patients*. That is, the Kampfe ‘847 reference clearly fails to teach or suggest the use of at least one per-patient disposable portion that connects at one end to the patient, as required by claim 13. Nor does Kampfe ‘847 teach or suggest a continual fluid path between the first and second fluid sources and the patient, as also required by claim 13.

Furthermore, as discussed above, the Wortrich ‘643 reference, on its own, also fails to discuss the use of a device adapted to mix fluids from the first and second fluid sources, as required by claim 13.

For at least these reasons, Applicant submits that none of the applied references, whether taken alone or in any reasonable combination, teach the claimed combination of elements recited by amended claim 13. As such, claim 13 is clearly patentable over these references. Applicant, therefore, respectfully requests the withdrawal of the rejection of claim 13, under §103(a).

Moreover, because claims 14-18 and 63-71 depend from claim 13, claims 14-18 and 63-71 are patentable by virtue of dependency as well as for their additional recitations. In addition, independent claims 72 and 82 recite similar features to claim 13, claims 72 and 82 are patentable for at least the reasons given with respect to claim 13. Further, because claims 73-81 depend from claim 72 and claims 83-94 depend from claim 82, claims 73-81 and claims 83-94 patentable by virtue of dependency as well as for their additional recitations.

III. Conclusion.

All matters having been addressed, Applicant respectfully requests the entry of this Amendment, the Examiner's reconsideration of this application, and the immediate allowance of all pending claims.

Applicant submits that the entry of this Amendment is proper under 37 C.F.R. §1.116 as the amendments: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not require any further consideration; (c) places the application in better form for an appeal, should an appeal be necessary.

Applicants' Counsel remains ready to assist the Examiner in any way to facilitate and expedite the prosecution of this matter. Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

PILLSBURY WINTHROP LLP



E. RICO HERNANDEZ
Reg. No. 47641
Tel. No. (703) 905-2088
Fax No. (703) 905-2500

ERH/smm
P.O. Box 10500
McLean, VA 22102
(703) 905-2000